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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,658	10/18/2001	Hakan Nygren	074022-2305	8741

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,658	NYGREN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7 and 8* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the amendment filed July 2, 2003. Applicants arguments and amendments have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

Terminal Disclaimer

2. The terminal disclaimer filed on July 2, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,060,237 and 6,355,429 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 4 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Humphries (U.S. Patent 4,849,330).

Humphries teaches supports comprising a smooth, flat surface and having attached thereto a nucleic acid complementary to a target nucleic acid (see col. 3 and

8). Humphries teaches matrixes which may comprise wafers having a smooth surface that is preferably flat and that the matrix will include a protective coating, preferably silicon oxide or silicon nitride (see col. 3). In combination, the surface may be reacted with organic silanes, which can provide for an organic coating of the surface (col. 3). The surface may have other materials bound thereto, including porous films, such as polyvinyl acetate, polyacrylates, proteins, or polysaccharide, e.g. agarose (col. 4). Preferably, the support comprises a glass surface having attached thereto nucleic acids, which are complementary to a target nucleic acid (col. 8). The smooth, flat glass surface is considered to be capable of reflecting light. Accordingly, the smooth, flat glass surface of Humphries, coated with silicon oxide or silicon nitride and having attached thereto a nucleic acid probe is considered to meet all of the limitations of the claimed supports.

RESPONSE TO ARGUMENTS:

In the response filed July 2, 2003, applicants state that they submitted arguments explaining the patentability of the claims in the parent case and that the examiner accepted those arguments and allowed the claims. It is asserted that because the present claims recite the same limitations of an optically smooth, flat, light-reflecting surface having a complementary nucleic acid bound thereto, the present claims should also be allowable. This argument is not convincing because the present claims are not of the same scope as those allowed in the parent application. The parent applications were not allowed merely because the claims referred to an optically smooth, flat, light-reflecting surface having a complementary nucleic acid bound thereto. The claims in

6,355,429 are all drawn to methods in which the binding of a target nucleic acid to the complementary nucleic acid results in an increase in mass on the light-reflecting surface. The claims of 6,060,237 are also drawn to methods in which a change in the light reflecting properties of a surface are determined. The claims in '237 also include a device having a light reflecting surface which has a first thickness when bonded to a second nucleic acid and a second thickness when a first and second nucleic acid are hybridized. The claims of '237 further include a support having an optically smooth, flat surface and **comprising a layer of silicon or aluminum as a light reflecting surface.** Accordingly, the present claims do not recite the same limitations as the claims that have been allowed.

Applicants state that Humphries teaches 2 separate supports, one that is photoresponsive and one that may bind a nucleic acid. Applicants incorrectly characterize the Office action as combining these two supports into one support. Applicants cite column 5 of Humphries as teaching that the support to which the DNA is bound may only be made of glass that is "transparent, opaque, [or] translucent." It is stated that such types of glass do not inherently reflect glass. These arguments have been fully considered but are not persuasive because Humphries does not in fact teach that the glass surface to which the nucleic acid is bound must be transparent, opaque or translucent. Rather, Humphries (column 8, lines 55-56) states "one could bind probes to a glass surface" – i.e., to any glass surface. At column 5, Humphries does not limit the support to only glass that is transparent, opaque or translucent. Rather, Humphries states that "the facing surface is normally rigid, and **may be** transparent, opaque,

translucent, **may be** metal, ceramic, **glass** or the like. Since Humphries teaches that the nucleic acid may be bound to any type of glass surface and since glass surfaces reflect some degree of light, it is maintained that Humphries teaches a support comprising an optically smooth, flat, light reflecting surface having a nucleic acid bound thereto. Again, Ii is noted that the present claims require an optically smooth, flat light-reflecting surface and the claims do not require that the complete support, such as the photoresponsive support, has the property of reflecting light to any particular degree

4. Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Diamond.

Diamond teaches that nucleic acids may be directly or indirectly attached to glass surfaces (see, for example, column 6). In particular, the nucleic acid may be directly covalently attached to the glass surface or may be indirectly attached to the surface via a linker. It is considered to be a property of glass that it is capable of reflecting light. Accordingly, in the absence of evidence to the contrary, the support of Diamond is considered to comprise an optically smooth, flat light-reflecting surface having a nucleic acid complementary to a target nucleic acid bound thereto.

RESPONSE TO ARGUMENTS:

In the response filed July 2, 2003, Applicants reiterate their argument that because claims have been allowed in the parent applications and because the present claims recite the same limitations of an optically smooth, flat, light-reflecting surface having a complementary nucleic acid bound thereto, the present claims should also be allowable. These arguments were addressed in paragraph 3 above and apply equally to the

present grounds of rejection. Furthermore, Applicants state that the "Examiner seems to be inappropriately asserting that the burden is on the Applicant to establish that Diamond does not disclose the claimed invention." This comment inappropriately mischaracterizes the previous office action. There is clearly no requirement in the previous Office action for Applicant to prove that Diamond does not disclose the claimed invention. The Office action states only that given the disclosure of Diamond it is considered to be a property of the glass support of Diamond that it is an optically smooth flat, light-reflecting surface and that it will be maintained that the support has this property unless evidence or objective arguments are presented to indicate otherwise. Applicants state that Diamond only discloses curved surfaces, such as the walls of a test tube, or particles or beads. However, the teachings of Diamond are in fact not limited to only curved surfaces. Rather, Diamond teaches that the nucleic acid may be attached to any type of glass support. While Diamond provides examples of a test tube and a particle or bead made of glass, the teachings of Diamond are not limited to only these types of glass supports.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humphries et al in view of Diamond (U.S. Patent No. 4,766,062).

Humphries teaches supports comprising a smooth, flat surface and having attached thereto a nucleic acid complementary to a target nucleic acid (see col. 3 and 8). Humphries teaches matrixes which may comprise wafers having a smooth surface that is preferably flat and that the matrix will include a protective coating, preferably silicon oxide or silicon nitride (see col. 3). In combination, the surface may be reacted with organic silanes, which can provide for an organic coating of the surface (col. 3). The surface may have other materials bound thereto, including porous films, such as polyvinyl acetate, polyacrylates, proteins, or polysaccharide, e.g.. agarose (col. 4). Preferably, the support comprises a glass surface having attached thereto nucleic acids, which are complementary to a target nucleic acid (col. 8). The smooth, flat glass surface is considered to be capable of reflecting light. Humphries does not specify the means by which the nucleic acid is attached to the glass surface.

Diamond teaches that nucleic acids may be directly or indirectly attached to glass surfaces (see, for example, column 6). In particular, the nucleic acid may be directly covalently attached to the glass surface or may be indirectly attached to the surface via a linker.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the nucleic acids to the glass support of Humphries either covalently or indirectly via a linker because Diamond teaches that these are effective methods for attaching nucleic acids to solid supports and these methods of attachment do not interfere with the hybridization of the immobilized nucleic acids to complementary target nucleic acids.

RESPONSE TO ARGUMENTS:

Applicants traverse this rejection for the same reasons set forth in paragraphs 3 and 4 above. Accordingly, the response to those arguments apply equally herein. Applicants state that "modifying Humphries according to Diamond would change the principle of operation of Humphries of measuring the flow of electrical current through a conduction medium (Humphries, Col. 2, lines 53-68). Diamond operates according to a principle of the displacement of labeled nucleotides." This argument has been fully considered but is not persuasive. Any differences in the "principles of operation" of Humphries versus Diamond are not relevant to the basis of the present grounds of rejection. Diamond was cited as teaching that a nucleic acid may be attached to a glass surface either directly or indirectly via a linker. Such a teaching would be applicable whether the resulting nucleic acid was to be used in a method that involved measuring

the flow of electrical current or a method that involved strand displacement. Accordingly, it is maintained that it would have been obvious at the time the invention was made to have attached the nucleic acids to the glass support of Humphries either covalently or indirectly via a linker because Diamond teaches that these are effective methods for attaching nucleic acids to solid supports and these methods of attachment do not interfere with the hybridization of the immobilized nucleic acids to complementary target nucleic acids.

6. Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
September 24, 2003

CARLA J. MYERS
PRIMARY EXAMINER